April 16, 2007

Dr. Carol O'Neill Mayhew Education Associate, Regulation Review Department of Education 401 Federal Street, Suite 2 Dover, DE 19901

RE: 10 DE Reg. 1513 [Health Related Regulations]

Dear Dr. Mayhew:

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Education's (DOE) proposal to adopt amendments to regulations covering the following: 1) immunizations; 2) school health record keeping; 3) physical examinations and screening; and 4) administration of medications and treatments. The proposed regulations were published as 10 DE Reg. 1513 in the April 1, 2007 issue of the Register of Regulations. Council has the following observations.

804 Immunizations

Section 1.0 defines a "school enterer" as a child older than 2 months being admitted to a Delaware School District. Under the Delaware Code, some children are eligible at birth, not two months of age. See 14 DE Admin Code 925, Section 4.1.1 which recites as follows: "The age of eligibility for special education and related services for children identified as having a hearing impairment, visual impairment, deaf blindness, or autism, shall be from birth through 20 years, inclusive."

Section 2.1.1 is a convoluted, unintelligible single sentence comprised of 101 words. It is also grammatically infirm. It reads as follows:

Four or more doses of diphtheria tetanus, pertussis (DtaP, DTP, or other approved vaccine) or a combination of these vaccines with the following exceptions: a child who received a fourth dose prior to the fourth birthday shall have a fifth dose; a child who received the first dose of Td (adult) at or after age seven may meet this requirement with only three doses of Td or Tdap (adult) one booster dose of Td or Tdap (adult) is recommended by the Division of Public Health for all students at age 11 or five years after the last DtaP, DTP or DT dose was administered whichever is later.

This "sentence" should be reformatted and divided into multiple sentences or subparts with subheadings.

There are several instances in which citations are placed in apposition rather than within parentheses. <u>See</u> four references to "14 <u>Del.C.</u> §131(a)(9)" in Sections 2.1.5.2; 3.2; 3.5; and 4.0. It would be preferable to place the citations in parentheses. <u>Compare</u> proposed Regulation 811, Section 3.1; and proposed Regulation 815, Section 1.1.2 and Section 2.2.2.

811 School Health Record Keeping

In Section 1.0, consider the following amendment: "..when the student experiences an acute exacerbation of a health condition, becomes sick, or is injured at school." Otherwise, the "emergency treatment card" is "underinclusive" and would not "capture" allergic reactions or episodic flare ups of chronic conditions. In contrast, the end of this section refers to "any medical conditions or allergies".

In Section 5.1, delete the extraneous hyphen.

815 Physical Examinations and Screenings

In Section 2.3.1.1, the first sentence is phrased as a DOE regulatory mandate that child care facilities and private nursery schools document lead screenings. While this is required by statute, the DOE has no authority to issue a regulation literally directing child care facilities to require screenings.

Section 2.3.1.1 omits the statutory exemption based on religious belief. <u>See</u> Title 16 <u>Del.C.</u> §2603.

Section 2.3.1.1 would literally preclude an 18 year old student transferring to a district from out-of-state from enrolling without lead screening documentation. Section 2.3 does not contain any age cut-off for requiring the lead screening. If the DOE intends to have no age cut-off, it would violate Title 16 <u>Del.C.</u> §2603 since the lead screening requirement only applies to children born after March 1, 1995. Section 2.3.2 ostensibly contains an extraneous "the". This section reads as follows: "The school nurse shall the document the lead screening on the Delaware School Health Record Form (see 14 DE Admin. Code 511)."

817 Administration of Medications & Treatments

The Department intends to bar a school nurse from administering a valid prescription if its dosage is not within FDA recommended guidelines. Section 3.2 reads as follows: Medications and dosages administered by the school nurse shall be approved by the Federal Drug Administration (FDA) and comply with FDA recommendations." In the preface to the regulations (p. 1514), the DOE provides the following rationale:

3.2 States that the medications and dosages must be FDA approved. Schools have been struggling with doctors writing large doses of antipsychotic medications to children, which are outside of the recommended doses. Also, parents bring in herbal medications. These later (sic "latter") medications have not been tested in children, do not have directions on proper dosing, nor does one know what side effects to look for.

Consistent with the attached materials, there are wide variations in how patients metabolize medications which may vary based on age, size, weight, health, and ethnicity. Moreover, FDA

standards are not "the Gospel". Delaware's Medicaid program explicitly authorizes deviation from FDA dosage standards:

a. Dosage limits: Medications are limited to a maximum dose recommended by the FDA, peer review journals that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional or national guidelines.

9 DE Reg. 420, 421 (September 1, 2005)

A school nurse should not disallow a child receiving a lower dose than recommended by the FDA or a higher dose recommended by the FDA. Literally, if a physician were titrating a child from a medication by slowly reducing dosage, and the dosage was less than the FDA recommended level, the nurse would be categorically precluded from administering the medication. In addition, a child could be prescribed a medication all summer, and when he/she returns to school, is literally not allowed to receive the prescribed medication. These are ridiculous results which could certainly hurt a child. If a nurse has a concern with a medication, she can contact the prescriber or pharmacy. However, as written, even if the nurse were informed by the pharmacy and prescriber that the dosage was safe and appropriate for the individual child, the nurse could not administer it if outside the FDA "recommended" (not mandatory) range.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations on the proposed regulations.

Sincerely,

Daniese McMullin-Powell, Chairperson State Council for Persons with Disabilities

cc: The Honorable Valerie Woodruff

Ms. Jean Allen

Ms. Martha Toomey

Ms. Paula Fontello, Esq.

Ms. Mary Cooke, Esq.

Ms Jennifer Kline, Esq.

Ms. Susan Keene Haberstroh

Mr. Charlie Michaels

Medical Society of Delaware

Psychiatric Society of Delaware

Dr. Jane Crowley, AI DuPont

Ms. Susan Cycyk, DCMHS

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